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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------|
| 10/714,333 | 11/14/2003 | Anastasia Khvorova | DHARMA 0100-US2 | 6379 |
| 23719 7590 04/18/2007 KALOW & SPRINGUT LLP 488 MADISON AVENUE 19TH FLOOR NEW YORK, NY 10022 | | | EXAMINER EPPS FORD, JANET L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 04/18/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/714,333

Applicant(s)

KHVOROVA ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 38-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 38-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. The previously indicated allowability of claims 1 and 38-60 set forth in the prior Office Action is withdrawn for the reasons set forth below.

Response to Amendment

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Those rejections set forth in the prior Office Action, but not repeated in the instant Office Action have been withdrawn in response to Applicant's amendment and/or arguments.

The amendment to claim 1 filed on 3-26-07 does not comply with the requirements of 37 CFR 1.121(c) because Applicants have not used an acceptable status identifier for this claim. Instant claim 1 recites the status identifier "previously introduced."

However, the only acceptable alternatives used to indicate a claim that was previously amended are: previously presented, previously amended; previously added; previously submitted; and previously presented claim.

Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c).

New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 43-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 55-57 recites the limitation "wherein said candidate siRNA is selected as said siRNA for the target gene if said candidate siRNA satisfies.....criteria selected from the group consisting of: the presence of.....a GC content of between about 30% and 52%, at least 2A or U bases at positions 15-19 of the sequence, and a internal repeat that is not stable at greater than 50°C" in claim 43. There is insufficient antecedent basis for these criteria in claim 58, since claim 43 does not provide antecedent basis for these criteria.

8. Claim 58 recites the limitation "wherein said candidate siRNA is selected as said siRNA for the target gene if said candidate siRNA satisfies each of the following criteria: a GC content of between about 30% and 52%, and a base other than G at position 13 of the sense sequence," in claim 43. There is insufficient antecedent basis for the criterion wherein the siRNA has a GC content of between about 30 and 52% in claim 58, since claim 43 does not recite this criterion.

9. Claim 60 recites the limitation "wherein said candidate siRNA is selected as said siRNA for the target gene if said candidate siRNA satisfies each of the following criteria:

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a GC content of between about 30% and 52%, a base other than G at position 13 of the sense sequence, and a internal repeat that is not stable at greater than 50°C" in claim 43. There is insufficient antecedent basis for these criteria in claim 60, since claim 43 does not mention the criteria wherein the siRNA has a GC content of between about 30 and 52%, and wherein the siRNA has an internal repeat that is not stable at greater than 50°C.

10. Claims 43, and those claims dependent therefrom recite the phrase "at least 79% similar," the metes and bounds of this phrase are vague and indefinite. Applicants define the term "substantially similar" at paragraph [0117] of the specification as filed, as referring to a similarity of at least 90% with respect to the identity of the bases of the sequence. However, it is unclear what 79% similarity is intended to encompass.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1 and 38-60 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

13. As noted in *State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

14. In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments. In the instant case, the claims are drawn to a method for selecting siRNA. However, the claimed method does not appear to be specific in nature, since the method of selecting does not appear to produce a concrete or tangible result, as the overall result of the method can be interpreted as merely designating an siRNA that satisfy the criteria set forth in the instant claims, without actually isolating the siRNA molecule physically.

15. Claims 1 and 38-60 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a physical transformation step.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
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JLE